

### **REMARKS**

This is in response to the Final Office Action mailed June 2, 2003. Claims 24-33 have been canceled, without prejudice. New claim 34 has been added. Claim 34 is currently pending and at issue.

No new matter has been added.

Entry of this amendment is respectfully requested, as it is believed to place the claims in condition for allowance or in better form for consideration on appeal.

### **Change of Inventorship**

Applicants acknowledge the Examiner's confirmation that all requirements for amendment of the inventorship have been fulfilled and that Luc Ouellet and Ruoxi Lan have been withdrawn as inventors.

### **Priority**

Applicants also acknowledge that Canadian Patent Application No. 2,294,459 has been confirmed as affording a priority date of October 4, 1999 for the present application.

### **Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 24-33 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter not supported by the specification. The Examiner states that this is a written description rejection.

Claims 24-33 have been canceled. Therefore, this rejection is rendered moot as to those claims.

New claim 34 has been added. It is respectfully submitted that claim 34 complies with the written description requirement of 35 U.S.C. § 112, first paragraph.

The subject matter of new claim 34 is similar to canceled claim 24, but claim 34 is limited to tethered tripeptides. Specifically, claim 34 calls for a macrocyclic compound made of a tripeptidomimetic backbone defined by formula (1). This tripeptidomimetic backbone comprises three amino acid fragments ( $A_1$ ,  $A_2$ , and  $A_3$ ) and a linker, herein called a tether (T). The tether is used as a linker between fragments  $A_1$  and  $A_3$  of the tripeptidomimetic backbone.

Reference to the specification establishes that claim 34 satisfies the written description requirement. A person of ordinary skill in the art having reviewed the specification would readily conclude that the present inventors were in possession of the compounds of claim 34. The specific features and substituents of the compounds are expressly defined by the structural formula in claim 34.

For example, the amino acid fragments are specifically identified at pages 6 and 7, and in Figure 1; the tethers are described at page 38, lines 6-12, and in Figure 1. For further clarity, attached Tables 1 and 2 identify the portions of the specification that specifically disclose the amino acids and tethers called for in claim 34.

The specification discloses representative examples of the claimed macrocyclic tripeptides (see, for example, pp. 25-27, Tables 1-3; and pp. 35-37, Tables 4-6). These examples constitute a representative cross-section of the compounds called for in the general formula set forth in claim 34. The Examiner has acknowledged (on page 5 of the Final Office Action) that examples of tethered tripeptides are set forth in the specification.

Additionally, the specification discloses methods of preparing several of the claimed compounds (see, for example, p. 33, line 23 to p. 37, line 7). These methods of preparation include detailed processing steps, such as particular reagents, filtrations, washes, and reaction times (see, for example, p. 34, line 21 to p. 35, line 5).

In *University of California v. Eli Lilly and Co.* ([CA FC] 43 USPQ2d 1398) the court stated that "a description of a genus ... may be achieved by means of a recitation of a representative number of [species] ..., falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus" (emphasis added). Here, the specification discloses a representative number of species that fall within the generic formula and also discloses representative examples of making the claimed compounds.

A review of the representative examples and the methods of preparation disclosed in the present specification would lead one of ordinary skill in the art to

conclude that the inventors were in possession of the compounds defined in claim 34 at the time the present application was filed.

**Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 24-33 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter not supported by the specification. The Examiner states that this is an enablement rejection.

Claims 24-33 have been canceled. Therefore, this rejection is rendered moot.

Applicants submit that the specification would enable a person of ordinary skill in the art to make and use the macrocyclic tethered tripeptides recited in claim 34. No further information beyond that disclosed in the instant specification would be required by those skilled in the art in order to make and use the compounds of claim 34.

The eight factors set forth in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) further support Applicants' assertion that the enablement requirements are satisfied with respect to claim 34, several of which are discussed below:

(1-2) Breadth of claims / nature of invention: The breadth of the claims (and the nature of the claimed invention) has been restricted to macrocyclic tethered tripeptides having particular amino acid side chains and tethers set forth in the claim. These amino acid side chains and tethers are supported by the specification as discussed above. The claimed compounds are similar in structure, all having the

three amino acid side chains and a tether component according to the general formula of claim 34.

(4) Level of ordinary skill: Given the disclosure in the specification regarding the particular compound structures (in both text and structural drawing format), the methods of preparing these particular compounds, and the particularly claimed substituents, a person of ordinary skill in the art would have all of the information needed to make and use the compounds of claim 34.

(6-7) Amount of direction provided by inventor / existence of working examples: The Examiner acknowledges (on page 11 of the Final Office Action) that examples of RGD analogs are provided in the specification. RGD analogs are examples of tethered tripeptides, to which claim 34 is limited. As discussed above, representative examples of tethered tripeptides are provided in the Tables and the text of the specification. These examples cover a representative cross-section of the compounds of claim 34 and, together the remainder of the specification, provide the guidance that would be required to enable one of ordinary skill to make and use the compounds of claim 34. In summary, the specification contains all of the information required to enable a person of ordinary skill in the art to make and use the claimed invention.

### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 24-33 have been rejected under 35 U.S.C. § 112, second paragraph, as indefinite. According to the Examiner, these claims were indefinite because it was unclear to the Examiner at what position the side chain groups were covalently attached to the macrocyclic compound, and how the bivalent radicals were covalently attached to the macrocyclic compound.

Claims 24-33 have been canceled. Therefore, this rejection is rendered moot.

Regarding claim 34, Applicants submit that the position of attachment to the macrocyclic compound is clearly identified with respect to all side chain groups and tethers.

### **Other Claim Rejections / Objections**

Claims 24-33 have been objected to as requiring correction of informalities; under 35 U.S.C. § 112, first paragraph, as containing subject matter not supported by the specification because, according to the Examiner, these claims contain new matter; and under 35 U.S.C. § 112, second paragraph, as indefinite. Claims 24-33 have been canceled. Therefore, these objections and rejections are rendered moot and are not applicable to new claim 34.

### **Conclusion**

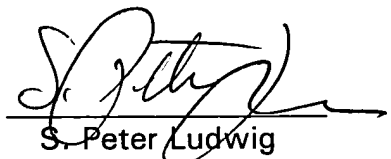
In view of the above amendments and remarks, this application is believed to be in condition for allowance and such action is earnestly solicited.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment,

the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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